DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP 15 2004

Thomas C. Green
Sidley Austin Brown and Wood, LLP
1501 K Street, N.W.
Washington, DC 20005

Re: Docket No. 2004P-0276

Dear Mr. Green:

This is a tentative response under Title 21 of the Code of Federal Regulations (CFR) section 10.30(e)(2)(iii) to your petition on behalf of Computerized Thermal Imaging Inc. (CTI), requesting that the Food and Drug Administration (FDA) initiate proceedings to permit CTI to supplement the administrative record in connection with CTI's premarket approval application (P010035). FDA is unable to issue a final response to your petition at this time because it is not clear to us exactly what action you are asking us to take.

In your petition, you state that CTI was severely and improperly prejudiced because of pervasive bias against the company by FDA staff reviewers. You then state that "CTI seeks leave under the citizen petition provisions, *see* 21 C.F.R. 10.30(h), to investigate and supplement the record concerning this bias. *See* 21 C.F.R. § 12.1, *et seq*." You then set forth a detailed explanation as to why you perceive bias by FDA reviewers against CTI.

It is not clear to us what information you believe is missing from the administrative record or in what manner you expect that it will be investigated and supplemented. Your reference to 21 CFR Part 12 is also unclear. Part 12 contains the FDA regulations on the procedures for a Formal Evidentiary Public Hearing ("Part 12 hearing"). In your petition, you do not specifically request a Part 12 hearing or establish the justification for a Part 12 hearing. Therefore, as required by 21 C.F.R. 10.30 (b), please state clearly what action or relief you are requesting.

It appears that you may be asking FDA to provide to you copies of records from FDA's files. If this is so, it would be considered a request under the Freedom of Information Act. See 21 CFR 20.23. If you are requesting records, please state clearly which records you are requesting so that FDA may respond to your request.

If you have any questions about this letter, please contact Joseph M. Sheehan of the Regulations Staff of FDA's Center for Devices and Radiological Health at 301-827-2974.

Sincerely,

William K. Hubbard
Senior Associate Commissioner
for Policy and Planning